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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,578	03/29/2004	Hagit Eldar-Finkelman	27457	2785

7590 11/18/2005

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/810,578	Applicant(s) ELDAR-FINKELMAN, HAGIT	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20050411</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's election of Group II in the response filed October 28, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3 and 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Applicants' response filed October 28, 2005.

2. The Sequence Listing filed March 29, 2005 is approved.

3. The claim for priority set forth in paragraph [0001] of the specification is objected to because of an incorrect asserted relationship between this application and parent application serial no. 09/951,902. This application discloses subject matter in addition to the subject matter disclosed in the parent application, i.e. this application discloses peptide inhibitors comprising an amino acid sequence which is part of a natural substrate of GSK-3. See claim 1, lines 8-9. The original disclosure of the parent application does not disclose natural substrates of GSK-3 in general, and does not disclose GSK-3 inhibitors which are derived from natural substrates of GSK-3 in general. Because this application discloses subject matter in addition to that disclosed in the parent application, the claim for priority should be amended to recite that this application is a continuation-in-part rather than a divisional of parent application serial no. 09/951,902. Correction is required.

4. Claims 1, 2, and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 1, lines 8-9, the phrase "a natural substrate of GSK-

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3 substrate” is unclear because substrates are not generally recognized as having their own substrates. It is believed that Applicant intended to refer to a natural substrate of GSK-3 enzyme, i.e. that the word “substrate” occurring after “GSK-3” should be deleted. The meaning of claim 8 is not clear. The claim appears to recite that if the upstream residue is Glu, then it is replaced with some other amino acid residue. Therefore the upstream residue can never be Glu, and the claim proviso is at best awkwardly worded.

5. Claims 1, 2, and 5-9 are objected to because of the following informalities: At claim 1, line 16, “to inhibit” should be re-written as “of inhibiting”. Appropriate correction is required.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not recite peptide inhibitors comprising an amino acid sequence which is part of a natural substrate of GSK-3. See claim 1, lines 8-9.

7. The effective filing date of instant claims 1, 2, and 7-9 is deemed to be March 29, 2004, the filing date of the instant application. Claims 1, 2, and 7-9 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/951,902 because the parent application ‘902, under the test of 35 U.S.C. 112, first paragraph, does not disclose peptide inhibitors comprising an amino acid sequence which is part of a natural substrate of GSK-3. Accordingly, the WO Patent Application 01/49709, which was published based upon grandparent application PCT/US01/00123, is available as prior art under 35 U.S.C. 102(b) against instant claims 1, 2, and 7-9. See MPEP 201.11(I)(B).

The effective filing date of instant claims 5 and 6 is deemed to be January 3, 2001, the filing date of parent application PCT/US01/00123. Instant claims 5 and 6 are not deemed to be

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entitled under 35 U.S.C. 119(e) to the benefit of the filing date of parent provisional applications 60/174,308 and 60/206,115 because the parent provisional applications, under the test of 35 U.S.C. 112, first paragraph, do not disclose polypeptides in which X can be any amino acid. Instead, the parent provisional applications are limited to polypeptides in which at least one X is proline.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/49709. The WO Patent Application '709 teaches the GSK-3 inhibitors derived from HSF-1. See page 30, Table 1, Peptide #7 and 8. The peptides are used pharmaceutically in combination with pharmaceutically acceptable excipients. See page 18, lines 3-7.

10. Claims 1, 2, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 97/33601. The WO Patent Application '601 teaches peptides identified as SEQ ID NOS:6 and 19, which have the same amino acid sequence as is recited in instant claim 1 and the same length as is recited in instant claim 2, and peptides identified as SEQ ID NOS:5, 10, 22, 26-31, and 33-38, which have the same amino acid sequence as is recited in instant claims 1, 7, and 8. The peptides are combined with pharmaceutically acceptable excipients. See, e.g., page 10, line 35 - page 11, line 15. In view of the similarity in structure between the peptides of the WO Patent Application '601 and the peptide inhibitors claimed by Applicant, the

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peptides of the WO Patent Application '601 are deemed inherently to be capable of inhibiting the enzymatic activity of GSK-3 to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptides of the WO Patent Application '601 and Applicant's claimed peptide inhibitors to shift the burden to Applicant to provide evidence that the claimed peptide inhibitors are unobviously different than the peptides of the WO Patent Application '601. Note also that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

11. Claims 5 and 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest peptides having the amino acid sequence and size recited in these claims.

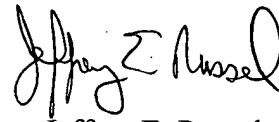
U.S. Patent No. 6,780,625 is cited as art of interest, but in view of the restriction requirement made in parent application serial number 09/951,902, an obviousness-type double patenting rejection of the instant claims over the claims of the '625 patent is not appropriate.

12. The Mitchell et al article (Cite No. 15) listed on the Information Disclosure Statement filed April 11, 2005 has been crossed off and not considered because a copy of the article does not appear to have been provided by Applicant, and because the citation is incomplete so that the examiner could not otherwise identify and locate a copy of the article. If Applicant will supply a copy of the article, the examiner will consider it and make it of record.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

November 15, 2005